510(k) Summary

MAR 1 9 2014

Submitter:	Edwards Lifesciences LLC
Contact Person:	Luke Meidell, Regulatory Affairs Associate III 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6212
Date Prepared:	February 17, 2014
Trade Name:	EMBOL-X Introducer Sheath
Classification Name:	Catheter Introducer 21 CFR Part 870.1340, Product Code DYB, Class II
Predicate Device:	K123714, EMBOL-X Introducer Sheath

Device Description:

Edwards Lifesciences' EMBOL-X Introducer Sheath is a 17 Fr, sterile, non-pyrogenic, single-use introducer made of flexible and non-flexible polymeric materials. It consists of a single lumen housing and a removable, snap-lock obturator.

The housing has a flexible suture flange for attachment to the vessel and orientation markings on the shaft and suture flange to assist in the placement of the EMBOL-X Introducer Sheath. Inside the housing is an internal valve to prevent backbleeding.

The housing also has suture loops on the proximal end of the Introducer housing, and vent grooves, vent holes, and a central lumen in the obturator that leads to the vent plug to assist in venting air from the Introducer.

The EMBOL-X Introducer Sheath is intended for use in procedures requiring the introduction of EMBOL-X Intra-Aortic Filters.

Indications For Use:

The Indications for Use for the EMBOL-X Introducer Sheath is as follows:

> *The EMBOL-X Introducer Sheath is indicated for use in procedures requiring the introduction of EMBOL-X Intra-Aortic Filters.*

Comparative Analysis:

The subject device has the same intended use and technological characteristics (i.e., design, material, chemical composition) as the predicate device. The subject EMBOL-X Introducer Sheath is comparable to the predicate device in fundamental scientific technology, materials, principles of operation, and functional performance evaluations. No new issues of safety or effectiveness have been raised as a result of the specification change or shelf life increase.

Functional/Safety Testing:

The following functional and accelerated aging bench testing was performed to support the specification change and the shelf life increase. All data met acceptance criteria, demonstrating that the device is as safe and effective as the predicate device.

- Leak Testing – Leak without device inserted, leak with obturator inserted, leak with filter inserted.
- Tensile Testing – Introducer bond joints, obturator vent plug bond joint.
- Additional Obturator Testing – Vent time, latch compression force, insertion force, removal and retention force.
- Filter Compatibility Testing – Insertion force, deployment capability, deployment force, retraction force, removal and retention force.
- Additional Introducer Testing – Suture flange flex
- Design Validation – Design was validated through surgeon evaluation and a bench top study

Conclusion:

Based on the Indications for Use, comparative analysis, and functional/safety testing results, the EMBOL-X Introducer Sheath is substantially equivalent to the predicate device and demonstrates no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

Edwards Lifesciences
c/o Luke Meidell
Regulatory Affairs Associate III
12050 Lone Peak Pkwy
Draper, Utah 84020

Re: K140398
Trade/Device Name: Embol-X Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 17, 2014
Received: February 18, 2014

Dear Mr. Meidell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K140398

Device Name: EMBOL-X Introducer Sheath

The EMBOL-X Introducer Sheath is indicated for use in procedures requiring the introduction of EMBOL-X Intra-Aortic Filters

Prescription Use x OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)